REMARKS/ARGUMENTS

Claims 1-6, 8-20 and 22-23 remain in this application. Claims 1 and 22 have been amended without prejudice to delete the term "as measured by weight loss on drying at 105 degrees Celsius" as suggested by the Examiner. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Rejection Under 35 USC 112, First Paragraph

Claims 1-5, 8-12, 15-20, 22, and 23 remained rejected under 35 USC 112, first paragraph. The Office Action asserts that "claims 1 and 22 lack written description because . . . the claim and specification because while the claims and the specification state that no more than a certain percent of water is left after drying at 105° C the time if which the dosage form is dried was not recited." See Page 2 of the Office Action. Applicants respectfully disagree. However, in the interests of furthering this Application to allowance, as discussed above, Applicants have amended claims 1 and 22 as suggested by the Examiner. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 USC 103

Claims 1-5, 8-12, 15-20, 22, and 23 remained rejected under 35 USC 103(a) as being unpatentable over Buehler et al. (US6432442) in view of McTeigue et al. (US 2002/0031552) in view of Dressman et al. (US5789393). See Page 4-7 of the Office Action. According to the previous office action of August 15, 2007 ("Previous Office Action"),

> "Buehler discloses a chewable pharmaceutical dosage form comprised by weight 1-20% gelatin, 10% hydrocolloid including HPC, up to 60% sweetener such as sorbitol and xylitol, [and] the matrix further contains 2-30% of a taste masked coated pharmaceutically active agent including ibuprofen. . . . Buehler does not disclose the exact taste masked coating as claimed by applicants and Buehler is silent on the MW and viscosity in 2% aqueous solution on the HPC matrix. McTeigue is used primarily for the disclosure within the taste masked pharmaceutical particles and chewable tablets made from those particles were well known in the art at the time of the invention . . . Dressman is used only to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. . . . Thus the claimed invention would have been prima facie obvious because the substitution of one known element such as a coating material disclosed within McTeigue for another known element such as the coating materials disclosed within Buehler would have yielded predictable results to one of ordinary skill in the art at the time of the invention."

See pages 5-6 of the Previous Office Action. Applicants again respectfully disagree.

As previously argued in the prior amendment of March 4, 2008 ("Prior Amendment"), the pending claims recite an immediate release compressed tablet dosage form "wherein said dosage form has a moisture content of not more than about 5 percent as measured by weight loss on drying at 105 degrees Celsius." Buehler et al. fails to disclose, or suggest, such a dosage form. Rather, Buehler at al. discloses a chewable gelatin matrix dosage form, not a compressed tablet. As discussed on pages 1-2 of the specification of the present application:

> [Buehler et al.] discloses the use of a gelatin matrix and an optional hydrocolloid as another technique for providing a soft, chewable delivery system. Because these "gummi" or confectionary systems also contain water in an amount of from about 10 to 30 percent by weight of the final product, they disadvantageously possess certain limitations with respect to shelf-life, packaging, and storage conditions. Additionally, it is economically more beneficial to produce other dosage forms such as, for example, compressed tablets, due to their simplicity of processing (emphasis added).

Specifically, Buehler et al discloses on col. 5, lines 18-22. "Water is used to hydrate both the gelatin and hydrocolloid, and makes up the remainder of the dry product weight. Water is present in the final product at levels of from about 10 to 30 weight percent, more typically, water is present at a level at about 20 to about 25 weight percent." Thus, Buehler et al. does not teach a compressed tablet, nor does it teach such a dosage form wherein the dosage form has a moisture content of not more than about 5 percent as recited in claims 1 and 22.

The Previous Office Action also asserted that "since the use of HPC within applicants claimed MW range was already well known to be useful in pharmaceutical compositions as shown by Dressman applicants claimed HPC was a known option available at the time of the invention and someone of ordinary skill in the art would have high expectation of success in using the specific MW of HPC disclosed within Dressman and substitute those for the HPC disclosed with McTeigue." Applicants again respectfully disagree.

While Dressman may disclose the use of such specific molecular weight of HPC as in the present invention, the reference does not disclose, or suggest, the use of such ingredient in a chewable tablet. The current Office Action asserts on page 6 that "since both references are at least related as pertaining to pharmaceutical formulations it would be expected that natural polymers that are the same such as HPC could be interchanged between the two references. Applicants, however, again do not agree with the assertion that someone of ordinary skill in the art would have a "high expectation of success" in using the ingredient in a compressed tablet.

Further, Applicants unexpectedly found benefits is using such an ingredient in the chewable compressed tablets of the present invention. As set forth on page 11, lines 3-13 of the specification of the present application:

> We have unexpectedly found that the addition of high weight average molecular weight hydroxyalkylcellulose to the matrix results in a dosage form that delivers a good mouthfeel through a rapid viscosity build without an initial intense drying sensation of the mouth and without a subsequent excessive slimy or gummy feel during mastication. Although the increase in viscosity will depend upon several factors such as, for example, the amount and molecular weight of such hydroxyalkylcellulose used and the amount and type of active ingredient, generally the use of about 0.1 percent to about 25.0 percent of a 60,000 to about 5,000,000 MW hydroxyalkylcellulose based upon the total weight of the dosage form, will result in a viscosity increase during tablet mastication that is similar to that obtained using gums, but without the drying sensation and without the subsequent excessive slimy or gummy feel imparted by using conventional agents.

In response to these unexpected benefits, the Advisory Action states that it is "an opinion of the inventor that is conclusionary and subjective in nature (taste and mouth feel) and is not sufficient enough of a showing of unexpected results to remove the previous 35 USC 103(a) rejection." Applicants again respectfully disagree, as certainly mouthfeel, including drying sensation, is clearly a benefit, even if it not capable of being analytically measured. Further, as argued above, Buhler et al. actually teaches away from the present invention by teaching a gelatin matrix dosage form with a high amount of water, not a compressed tablet.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP-5014/WEM.

Respectfully submitted,

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